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RULES
OF
THE TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

CHAPTER 0720—4
CERTIFICATE OF NEED PROGRAM—GENERAL CRITERIA[1]

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0720—4—.01 GENERAL CRITERIA FOR CERTIFICATE OF NEED. The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:"

(1) Need. The health care needed in the area to be served may be evaluated upon the following factors;

(a) The relationship of the proposal to any existing applicable plans;

(b) The population served by the proposal;

(e) The existing or certified services or institutions in the area;

(d) The reasonableness of the service area;

(e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, Tenncare participants, and low-income groups;[3]

(f) Comparison of utilization/occupancy trends and services offered by other area providers;

(g) The extent to which Medicare, Medicaid, Tenncare,[4] and medically indigent patients[5] will be served by the project.

(h) In determining whether the above criteria are met, the Agency shall consider what steps the applicant has taken to assess that providers of services which will operate in conjunction with the project will also meet these needs.[6]

(2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors.

(a) Whether adequate funds are available to the applicant to complete the project;

(b) The reasonableness of the proposed project costs;

(e) Anticipated revenue from the proposed project and the impact on existing patient charges;

(d) Participation in state/federal revenue programs;

(e) Alternatives considered; and

(f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.

(3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:[7]

(a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, affiliation of the project with health professional schools);[8]

(b) The positive or negative effects attributed to duplication or competition;

(c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;

(d) The quality of the proposed project in relation to applicable governmental or professional standards.[9]

(4) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site for a proposed new health care institution, the Agency may consider, in addition to the foregoing factors, the following factors:

(a) Need. The applicant should show the proposed new site will serve the health care needs in the area to be served a least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change the proposed new site.

(b) Economic factors. The applicant should show that the proposed new site would be at least as economically beneficial to the population to be served as the original site.

(c) Contribution to the orderly development of health care facilities and/or services. The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.[10]

***Authority**: T.C.A. §§68—11—1605; 68—11—1609; 4—5—202.*

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[1] Jerry W. Taylor, Esq. of Farris Mathew Branan Bobango & Hellen made the following comments:

> The "general criteria" has served the CON process well over the years, as guidance in making CON decisions and should not be significantly changed.
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> I would echo the frustrations expressed by another commenter of having to repeat the same information numerous times in the application, which results from having to specifically respond to the "general criteria" in the application. The CON application as it now stands tracks the "general criteria" very closely, albeit not verbatim. Therefore, once the questions in the CON application have been answered, having to then respond specifically to the "general criteria" results in numerous repetitions of the same information.

[2] E. Gramam Baker, Jr., Esq. of Weeks, Anderson and Baker submitted the following comments:

> I suggest this entire section be deleted.
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> These questions originated by representatives of the old Health Systems Agencies ("HSA" -- there were 6 in TN, based on geographic regions of the State) years ago. The questions were designed to give the HSA boards additional information that wasn't covered in the CON application. I was on that committee, and remember the process well. The questions were addressed by the reviewers – not the applicants. We gave that information to our respective Boards, who met one month prior to the former HFC, and made formal recommendations to the HFC regarding each project.
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> Unfortunately, someone found an old copy of the questions years ago – maybe they were included in an old State Health Plan or something – and decided it would be great if all applicants answered these questions, also, in addition to answering all of the questions in the ever-changing CON application.

Obviously, there are a great many redundancies with these questions, both in and of themselves, and in light of the changes that have occurred in the CON application itself over the years.

As someone who prepares a lot of CON applications, it is distressing to have to answer the same question over and over, repeating answers to these questions that have somehow survived for almost 30 years. For example, questions concerning alternatives that were considered prior to filing any particular CON application abound. Further, the service area, population to be served, etc. is addressed in multiple locations, as are questions about the reasonableness of the project costs and financing mechanisms.

I strongly suggest that this entire section be removed, and then include any pertinent questions in a new CON application – asking any particular question only one time. This would entail devising a new application form, but most people I'm aware of, including Agency staff, have said that the application form needs to be changed. Again, as someone who writes a lot of applications, questions are asked over and over, plus, the reviewers ask a lot of (supplemental) questions that are neither in the application nor in the sets of criteria (general or specific) that are currently adopted. This is extremely frustrating.

I'm aware that the Agency staff is fully capable of designing a new CON application form. However, if time is of the essence and if the staff desires outside input, I would be happy to serve on a committee to help draft a new application form that asks questions one time, especially if applicants did not have to respond to multiple questions on general criteria forms. With the internet and e-mail capabilities, a draft could be circulated quite easily among committee members who could submit something to the staff, who could then submit something to the Agency for public comment. The new application form could then go through the rule-making hearing process and (hopefully) be adopted by the Agency.

[3] Suggested by Commissioner Flowers "to reflect the Agency's directive to weigh the needs of TennCare/Medicaid recipients as prescribed by T.C.A. § 68-11-1605. . ."
[4] Agency Staff proposed the addition of "Tenncare." Dr. Shackleford concurred with the proposal.
[5] Dr. Nancy Blank, State Health Planning and Advisory Board member and Chair of its Task Force for Development of Criteria & Standards for Certificate of Need, proposed that "medically indigent patients" be replaced with "low income groups" because the new language reflects current statutory language. However, interested parties have suggested that such a change in language would materially change the individuals referenced (i.e., it is possible to be of a "low income group, but yet not be "medically indigent").
[6] See footnote #3, above.
[7] Dr. Nancy Blank, member of the State Health Planning and Advisory Board, proposed that the following be added as a subsection of 0720-4-.01(3):

> () Conforming to the goals for quality health care for Tennesseans as set forth in the State Health Plan outlined by the State Health Planning and Advisory Board.

Dr. Blank's proposed amendment to the Agency's Rules is supported by two sections of the new statute. T.C.A. § 68-11-1602(18) defines "State Health Plan" as "the plan that is developed by the state planning and advisory board pursuant to this part (specifically, §68-11-1625). The plan shall include clear statements of goals, objectives, criteria and standards to guide the development of health care programs administered or funded by the State of Tennessee through its departments, agencies or programs, and used by the agency when issuing certificates of need." Further, T.C.A. § 68-11-1609 states, in part, that in making determinations (of whether need, economic feasibility & contribution to the orderly development of healthcare have been demonstrated), "the agency shall apply the goals, objectives, criteria and standards in the state health plan, developed in accordance with T.C.A. § 68-11-1625."

Since T.C.A. § 68-11-1609 references the Agency's application of the state health plan to not solely contribution to the orderly development of healthcare, but also to need and economic feasibility, *Staff would propose that if the amendment be made, that the amendment be made as a separate subsection of 0720-4-.01, and not as part of subsection (3).* Staff would suggest that the goal of Dr. Blank's proposed amendment to 0720-4-.01(3) could be accomplished by using the same language as T.C.A. § 68-11-1609, as follows:

() In making determinations of whether the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective healthcare facilities and/or services, the Agency shall apply the goals, objectives, criteria and standards in the state health plan, developed in accordance with T.C.A. § 68-11-1625.

Mr. John Wellborn of Development Support Group submitted the following comment:

> The statutory language of TCA 68-11-1609 requires the Agency to "apply" all substantive parts of the State Health Plan when it becomes available--not just the goals.
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> However, based on three decades of dealing with State Plans in many States, we believe that the Agency will likely encounter CON situations where the Plan's specific project review criteria, if strictly applied, would conflict with general goals and objectives. Certainly that has been the Agency's consistent experience with today's Guidelines for Growth. It is very optimistic to assume that any Health Plan process can avoid all such limitations and that this will not happen again.
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> So if it is necessary to make this new rule at all, before even seeing the Health Plan, hopefully the Agency will combine Dr. Blank's and the staff's approaches into something like the following:
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> "…the Agency shall apply the goals, objectives, criteria and standards in the State Health Plan developed in accordance with TCA 68-11-1625, provided, however, that all such decisions shall be consistent with the goals for quality health care for all Tennesseans."

[8] Commissioner Flowers has suggested the following, *which proposal has been neither approved nor denied yet by the Agency*:

"To reflect the Agency's directive to weigh the needs of TennCare/Medicaid recipients as prescribed by T.C.A. § 68-11-1605, I would add the following to 0720-4-.01 (3)(a):

> (a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreement for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);"

[9] The A.A.R.P. submitted the following proposal with respect to subsection (d):

> (d) The quality of the proposed project in relation to applicable governmental or professional standards. In making determinations whether the proposed acquisition of a nursing home or the acquisition or expansion of home health or other long term care services satisfies this requirement, the Agency shall consider whether the applicant or any affiliated or predecessor entity has been found, within the past five years to have violated nursing home quality or resident rights standards, and has been subjected to a Type A or Type B civil monetary penalty, or to an equivalent sanction by the federal government or appropriate regulatory authority of another state, for such violation. Except as otherwise provided by T.C.A. §§ 68-11-1609(b) and 1621, the same criteria shall apply to applications for new nursing home beds.
>
> COMMENT:
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> This addition is consistent with T.C.A. § 68-11-1609(b). That statute requres that the Agency determine whether to grant certificates of need based on whether the proposal will contribute to the "orderly development of adequate and effective health care facilities and/or services". The Agency is to make that determination by applying the "goals, objectives, criteria and standards in the state health plan, developed in accordance with § 69-11-1625", which states that "it is the policy of the State of Tennessee that "every citizen can have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers …"

Among the best evidence of whether the proposed acquisition or expansion will provide "adequate and effective" services is the track record of the parties that will be involved in the provision of such services, as reflected in the imposition of civil monetary penalties for substandard or dangerous care. The suggested language requires consideration of only those penalties imposed for the more serious infractions of resident rights or quality standards, and such consideration would be limited to the past five years.

Without considering these criteria, citizens cannot have confidence that "the quality of health care is continually monitored and standards are adhered to by health care providers".

The provision applies to the expansion or acquisition of home health and home or community-based services, as well as nursing home care, where the applicant has a record of providing nursing home care, since the quality of care provided in nursing homes is relevant to assessing the likely quality of other health services the applicant is likely to provide. The last sentence acknowledges that, in the case of some applications for *new* nursing home beds, the separate statutory provisions of T.C.A. §§ 68-11-1609(b) and 1621 govern.

[10] Commissioner Flowers has proposed that the following subsection be added "[t]o clarify the authority of the Agency to impose conditions on certificates. . ." The Agency has yet to determine whether to incorporate the proposal.

Certificate of need conditions. In accordance with T.C.A. § 68-11-1609, the Agency, in its discretion, may place such conditions upon a certificate of need it deems appropriate and enforceable to meet the applicable criteria as defined in statute and in these rules.